



REMARKS

Claims 13-27 are pending in the instant application and under consideration.

I. The Amendments

The claims have been amended, without prejudice, for the purpose of more clearly defining what Applicants regard as their invention. The amendments do not introduce new matter, and they are fully supported by the specification and the claims as originally filed. Therefore, entry pursuant to 37 C.F.R. § 1.111 is respectfully requested.

Specifically, Claims 13, 15, 20, 22, 24, and 26 have been amended to recite “wherein said nucleic acid comprises the complete *adenovirus* 5 sequence [...].” This amendment is supported in the specification, *e.g.*, in Example 1. See, Substitute Specification at page 5, lines 15-19. Claim 17 has been amended to recite its proper dependency from Claims 13, 14, 15, and 16. Finally, Claims 14, 16, 21, 23, 25, and 27 have been amended to read in independent form.

II. The Rejections

A. The Rejection of Claims 13-27 Under 35 U.S.C. § 112, Second Paragraph

Claims 13-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner objects to the phrase “AAV 5 sequence with the exception of the E1 region.” This rejection is obviated and/or overcome in view of the amendment to the claims, which now recite “*adenovirus* 5 sequence with the exception of the E1 region.”

In view of the above, the rejection of Claims 13-27 under 35 U.S.C. § 112, second paragraph should be withdrawn.

B. The Rejection of Claims 13-27 Under 35 U.S.C. § 112, First Paragraph

Claims 13-27 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that the specification does not provide a written description for an “AAV 5” sequence or an “AAV 5 sequence with the exception of the E1 region and/or L1 region.” The rejection is obviated and/or overcome in view of the amendment to the claims, which now recite “*adenovirus 5* sequence with the exception of the E1 region.”

In view of the above, the rejection of Claims 13-27 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

C. The Rejection of Claims 5, 6, 8, 9, 13, 15, 17, 19, 20, 22, 24 and 26 Under 35 U.S.C. § 102(e)

Claims 13, 15, 17, 19, 20, 22, 24 and 26 are rejected under 35 U.S.C. § 102(e) as being anticipated by Colosi, United States Patent No. 6,004,797 (“Colosi”). Further, Claims 5, 6, 8, and 9¹ are rejected under 35 U.S.C. § 102(e) as being anticipated by Wang *et al.*, United States Patent No. 5,872,005 (“Wang”). These rejections are respectfully traversed.

The Legal Standard. The standard governing anticipation under 35 U.S.C. § 102 is one of strict identity (*see* M.P.E.P. § 2131). The Court of Appeals for the Federal Circuit has held that anticipation can be established only by a single reference that teaches each and every element of the claimed invention; anticipation is not shown even if the differences between the claims and the cited reference are argued to be “insubstantial” and the missing elements could be supplied by the knowledge of one skilled in the art (*Structural Rubber*

¹ Claims 5, 6, 8, and 9 have been previously cancelled, and a cancelled claim cannot be rejected. Yet, Applicants are using this opportunity to point out that Wang is indeed not applicable to any of the presently pending claims.

Prod. Co. v. Park Rubber Co., 223 USPQ 1264 (Fed. Cir. 1984)). Furthermore, in *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985) the court pointed out that the assertion of invalidity for lack of novelty is erroneous if a reference teaches “substantially the same thing.” A cited reference must meet each claim limitation in order to constitute anticipation.

The Claimed Invention. The presently claimed invention is directed, *inter alia*, to a nucleic acid comprising an AAV helper virus sequence developing AAV viral particles, wherein said nucleic acid comprises the complete adenovirus 5 sequence with exception of the E1 region. *See*, Claim 13. The present invention is further directed to a method for producing an rAAV viral particle preparation which is not contaminated with helper virus using the claimed nucleic acids. Applicants respectfully submit that neither Colosi nor Wang anticipate the presently claimed invention.

The Rejection Over Colosi. Colosi teaches, according to the Examiner’s characterization, a method of producing AAV viral particles without using a helper virus. The non-helper virus accessory functions, needed for AAV particle release, can be derived from adenovirus, herpesvirus and vaccinia virus. *See*, Office Action at page 5. Colosi, however, does not teach or suggest the use of an AAV helper virus sequence that comprises the complete adenovirus 5 sequence with exception of the E1 region, as the presently claimed invention. Therefore, Colosi cannot anticipate present Claims 13, 15, 17, 19, 20, 22, 24, or 26.

In view of the above, the rejection of Claims 13, 15, 17, 19, 20, 22, 24 and 26 as anticipated under 35 U.S.C. § 102(e) by Colosi is in error and should be withdrawn.

The Rejection Over Wang. Wang discloses, according to the Examiner’s interpretation, a method of producing helper virus free AAV viral particles using a cell line

that contains the non-AAV complementing sequences necessary for AAV packaging.

However, Wang does not teach or suggest the use of AAV helper virus sequences comprising the complete AAV 5 sequence with exception of the E1 region for developing AAV viral particles, as the presently claimed invention. Thus, Wang cannot anticipate any of the present claims.

In view of the above, a rejection of any of the present claims as anticipated under 35

U.S.C. § 102(e) by Wang is in error and should be withdrawn.



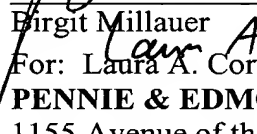
CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 493-4935. The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 16-1150 (order no. 8484-101-999) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: September 10, 2003


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